**REMARKS**

Restriction has been required between what the PTO deems to be seven patentably distinct inventions, namely:

Group I, presently comprising claims 1-9, 17, 21-23, 26, and 27, and drawn to nucleic acids encoding a polypeptide capable of binding to RIP and modulating or mediating its intracellular activity;

Group II, presently comprising claims 10-12, and 24, and drawn to antisense nucleic acids and methods of use;

Group III, presently comprising claims 13-16, and drawn to a polypeptide capable of binding to RIP and modulating or mediating its intracellular activity;

Group IV, presently comprising claims 18 and 19, and drawn to antibodies;

Group V, presently comprising claims 20, 26 and 27, and drawn to method of modulating RIP-modulated effects by administering a polypeptide capable of binding to RIP and modulating or mediating its intracellular activity;

Group VI, presently comprising claim 25, and drawn to methods of making polypeptides capable of binding to RIP and modulating or mediating its intracellular activity; and

Group VII, presently comprising claim 27, and drawn to methods of modulating RIP-modulated effects by administering a

nucleic acid encoding a polypeptide capable of binding to RIP and modulating or mediating its intracellular activity.

Applicant hereby respectfully and provisionally elect with traverse Group III, directed to a polypeptide capable of binding to RIP and modulating or mediating its intracellular activity and presently comprising claims 13-16.

The restriction requirement is respectfully traversed insofar as the antibody of claim 18 is considered to be an independent and distinct invention from the polypeptide of claim 13. Applicants hereby concede that, if the polypeptide of claim 13 were available to the prior art (which includes knowledge of its biological activity as set forth in the claim), it would be *prima facie* obvious, within the meaning of 35 USC 103, for one of ordinary skill in the art to make an antibody which is specific to such polypeptide. Techniques of raising antibodies, such as monoclonal antibodies, are well known and the Patent and Trademark Office routinely rejects claims to monoclonal antibodies, in general, as being obvious if the polypeptide against which it is specific is known in the prior art.

It should clearly be understood that the present admission is a one-way admission only. Applicants do not concede that if an antibody is known which happens to bind to the polypeptide of claim 13, this would necessarily make the polypeptide of claim 13 obvious or unpatentable. Furthermore, applicants do not concede that <u>all</u> monoclonal antibodies specific

for the polypeptide of claim 13 are necessarily obvious. Specific monoclonal antibodies may exist having unexpected properties which would not be obvious from prior art knowledge of the polypeptide to which it is specific. However, in the present case, claims 18 and 28 are broad claims to any antibody or to any monoclonal antibody, respectively, specific to the protein of claim 13 and the present concession is simply that there are antibodies within the scope of claim 18 which would be *prima facie* obvious in the sense of 35 USC 103 if the polypeptide of claim 13, including its biological properties, were known in the prior art. Knowing the biological activity of such polypeptide, one of ordinary skill in the art would have been motivated to make a monoclonal antibody for the purpose of immunoaffinity purification or for the purpose of blocking its activity. The techniques for doing so are well known.

In light of the present admission and the provisional election of the polypeptide claims of Group III, a restriction requirement cannot be maintained. If the elected polypeptide claims proceed to issue, any patent issuing on the antibody would have to be subject to an obviousness-type double patenting rejection in view of the above admission. See MPEP §804.II.B.1. relating to double-patenting rejections, which states:

> In determining whether a non-statutory basis exists for a double-patenting rejection, the first question to be asked is - Does any claim in the application define an invention that is merely an obvious variation of an invention claimed

> in the patent? If the answer is yes, then "obvious-type" non-statutory double-patenting rejection may be appropriate.

However, such a double patenting rejection cannot be made in light of 35 USC 121. Reference is made to Section 803.01 of the MPEP, where it states:

> Notwithstanding the fact that this section of the statute [35 USC 121] apparently protects the applicant against the dangers that previously might have resulted from compliance with an improper requirement for restriction, IT STILL REMAINS IMPORTANT FROM THE STANDPOINT OF THE PUBLIC INTEREST THAT NO REQUIREMENTS BE MADE WHICH MIGHT RESULT IN THE ISSUANCE OF TWO PATENTS FOR THE SAME INVENTION. [Emphasis original]

See also 37 C.F.R. §1.601(n) defining the concept of patentably distinct inventions from the interference perspective. This rule states:

> Invention "A" is the **same patentable invention** as an invention "B" when invention "A" is the same as (35 USC 102) or is obvious (35 USC 103) in view of invention "B" assuming invention "B" is prior art with respect to invention "A".

Here, assuming the polypeptide of claim 13 (invention "B") is prior art to the antibody of claim 18 (invention "A"), the antibody is *prima facie* obvious in light of applicant's admission. Thus, both claims are drawn to the same patentable invention. If they are drawn to the same patentable invention for interference purposes, they should be considered the same patentable invention for all purposes, despite any distinction in the material *per se*. As indicated above, no restriction requirement can be properly

made which would result in the issuance of two patents for the same invention.

MPEP §803 refers to the case of In re Lee, 199 USPQ 108 (Deputy Asst. Comm'r. for Pat's 1978) as requiring that restriction should not be required if there is an express admission that the claimed inventions are obvious over each other within the meaning of 35 USC 103. However, such a two-way admission is not necessary as even the one-way admission presently being made is sufficient to result in two patents directed to the same invention. If an antibody claim in one patent would be obvious from a polypeptide claim in another patent, then the two claims are not patentably distinct and the imprimatur of MPEP §803.01 quoted herein above must be invoked.

It should be noted that this identical issue has already been made the subject of a petition to the Commissioner with respect to another case handled by the firm of Browdy and Neimark P.L.L.C., and Deputy Director Mary C. Lee confirmed that, in such a circumstance, restriction requirement is not applicable. A copy of that decision is attached hereto. Note particularly where it states:

> At this point it is noted that the fact that there is an admission that the antibody is obvious in view of the peptide but not an admission that the peptide is obvious over the antibody would not change this decision because the Office policy that "no restriction requirements be made which might result in the issuance of two patents for the same invention" would still control.

If claim 18 cannot be restricted from claim 13, then claims 18 and 28 must be examined with the elected claims 13-16, as claims 18 and 28 are not patentably distinct from claim 13.

Claims to non-elected Groups I, II, VI and VII have been canceled. It is understood that the claims of Group V will be rejoined under rejoinder practice in accordance with MPEP 821.04. The claims of Group V are directed to methods of using the product of the elected Group III claims. MPEP 821.04 states:

> However, if applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims which depend from or otherwise include all the limitations of the allowable product claim will be rejoined.

Withdrawal of the restriction requirement to the extent requested herein and examination and allowance of all the claims now present in the case are therefore earnestly solicited.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

Claims 18 and 19 have been amended as follows:

18(Once-amended). ~~Antibodies or active fragments or derivatives~~ An antibody or active fragment or derivative thereof, specific for a polypeptide according to claim 13.

19(Once-amended). A method for modulating RIP modulated/mediated effect on cells, comprising treating said cells with ~~antibodies or active fragments or derivatives~~ the antibody or active fragment or derivative thereof according to claim 18, said treating being by application of a suitable composition containing said ~~antibodies, active fragments or derivatives~~ antibody or active fragment or derivative thereof to said cells, wherein when the RAP protein or portions thereof of said cells are exposed on the extracellular surface, said composition is formulated for extracellular application, and when said RAP proteins are intracellular said composition is formulated for intracellular application.